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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,173	12/04/2008	Hitoshi Endou	65445(71526)	3295

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EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,173	ENDOU ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/11/2006; 03/26/2008;11/03/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II (claims 5-11) in the reply filed on 11/11/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-11 are pending; claims 1-4 are withdrawn as being drawn to non-elected subject matter. Claims 5-11 are presently examined.

Priority

2. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Also, in the first paragraph of the specification, Applicant should identify the fact that the Application is a National Stage entry of PCT/JP2004/016671 filed 11/11/2004.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 05/11/2006, 03/26/2008 and 11/03/2008 were considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, it is unclear if the cell line is expressing URAT1 in the presence of a test compound, in the absence of it or is expressing it constitutively. The methods claimed in claims 5-11 lack positive steps to perform the method as well as a step concluding the result of the methods. In the claim 6, reference is made to a method according to claim 4, but there is no method presented in claim 4.

As such, the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Endou et al. (CA 2456172- published 04/03/2003- cited by Applicant).

8. Endou et al teach a novel urate transporter gene participating in the urate transport in the kidney and a urate transporter which is a polypeptide encoded by the above gene (abstract). The protein product is named URAT1 and has the same amino acid sequence as the protein used in the instant Application. Furthermore, Endou et al. provides a screening method of a substance having modulatory action for the uric acid transport. The URAT1 works for transporting uric acid into the cells and is deeply involved in the reabsorption of the uric acid. Also, as is shown in Figures 6, 8, 9 and 10, it is possible to quantify the accelerating or inhibiting action for uric acid uptake of the screening substance in the system where the URAT1 is expressed, by adding uric acid to the system, further adding the screening substance thereto, and comparing a uric acid uptake amount with that in the case with no addition of the screening substance. As is shown in Figures 6 and 8, the substances clinically used as uricosuric accelerators have remarkably inhibited the uptake of uric acid in the above experimental system, and thus, it is shown that it become possible to screen the uricosuric accelerating action of the screening substance in this system. As the cells used in this screening system, the cells are not limited to oocytes used in the following experiments, and it is possible to use various living cells as long as the cells can express URAT1.

The modulators identified can regulate the uptake of uric acid by the urate transporter involved in the urate transport in the kidney, and therefore can be used as

an active ingredient of the medicines for the treatment/prevention of various diseases associated with the reabsorption of uric acid such as hyperuricemia and gout. It is possible to make the obtained active ingredient a pharmaceutical composition using a pharmacologically acceptable carrier (p.10-11). This may be used in humans, where hyperuricemia becomes a risk factor for cardiovascular diseases and hypertension (p.1).

Therefore, Endou et al. teaches the method for screening substances having uricosuric regulating action using URAT1.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Endou et al. (CA 2456172- published 04/03/2003- cited by Applicant) in view of Kanellis et al. (Uric Acid Stimulates Monocyte Chemoattractant Protein-1 Production in Vascular Smooth Muscle Cells Via Mitogen-Activated Protein Kinase and Cyclooxygenase-2, Hypertension, 41, 1287-1293, 2003) and Hurteau et al. (Transforming growth factor beta inhibits proliferation of human ovarian cancer cells obtained from ascites, Cancer, 74, 93-99, 1994).

The claims are drawn to methods of screening a substance efficacious for healing, preventing or treating vascular disorders, hypertension, and renal disorders, the methods comprising using a cell line expressing URAT1 in the presence or absence of a test compound; and assaying the proliferation ability of the cells or the amount of a monocyte chemotactic factor (MCP-1) produced by the cells. The proliferation ability of the cells is assayed by measuring the thymidine uptake level by the cells.

The teachings of Endou et al. were presented *supra.* They are silent of assaying the proliferation of the cells in the screening process by thymidine incorporation as well as about the quantitation of MCP-1 in response to the screening process.

Kanellis et al. teach that soluble uric acid can induce vascular smooth muscle cells proliferation, activated through ERK, MAPK Cox-2 or PDGF pathways (introduction). Also taught is that uric acid increases the production of MCP-1 protein in rat VSMC (p.1289, left col., last paragraph). The teachings of Kanellis et al. underscore the pathogenic role of uric acid in hypertension, vascular disease and atherosclerosis (p. 1292, left col. third paragraph.

Hurteau et al. exemplify a well known and routinely use of thymidine incorporation assay for determining cell proliferation (abstract and Material and methods).

Since the uric acid, in order to exert its effects, necessarily has to be transported in the cells by a transporting mechanism and, in view of Endou et al., this is through URAT1, identifying modulators of URAT1 can, in view of Hurteau et al and Kanellis et al. be performed by proliferation assays or by detection of MCP-1.

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to employ the teachings of Hurteau et al. and Kanellis et al. in the methods of Endou et al. with a reasonable expectation of success, because the assays were routinely used in the art and Kanellis et al. showed the usefulness of employing VSMC in finding modulators in uric acid pathogeneses.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 5-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,510,847 (which has the same assignee as the instant Application). Although the conflicting claims are

not identical, they are not patentably distinct from each other because the transporter used in the method of screening of the patent is the same and the method has the same outcome as in the instant Application.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elly-Gerald Stoica/
Examiner, Art Unit 1647